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C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation	MDL NO. 15-02641-PHX-DGC
This Document Relates to:	
DEAN BECKER, an individual, Plaintiff, v. C. R. BARD, INC., a Delaware Corporation; AND BARD PERIPHERAL VASCULAR INC., an Arizona Corporation, and DOES 1-100, inclusive, Defendants.	Case No. CV-15-2155-PHX-DGC **DEFENDANTS C. R. BARD, INC. AND BARD PERIPHERAL VASCULAR, INC.'S ANSWER AND AFFIRMATIVE DEFENSES AND DEMAND FOR TRIAL BY JURY**

Defendants C. R. Bard, Inc. ("Bard") and Bard Peripheral Vascular, Inc. ("BPV") (Bard and BPV are collectively "Defendants") answer the Complaint ("Plaintiff's Complaint") of Plaintiff Dean Becker ("Plaintiff") as follows:

PARTIES

1. Defendants are without information sufficient to form a belief as to the truth of the allegations contained in Paragraph 1 Plaintiff's Complaint and, on that basis, deny them.

2. Defendants deny that Bard is a Delaware corporation. By way of further answer, Defendants admit that Bard is a New Jersey Corporation with its principal place of business in New Jersey, and that Bard does business, and is authorized to do business, in the State of California. Defendants admit that Bard owns a facility where vena cava filters are manufactured, including under the trademarks G2®, G2® Express, and G2®X Filter Systems. Defendants deny any remaining allegations contained in Paragraph 2 of Plaintiff's Complaint.

3. Defendants admit that BPV is an Arizona Corporation, and that BPV does business, and is authorized to do business, in the State of California. Defendants further admit that BPV is a wholly owned subsidiary of Bard. Defendants also admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV has designed, sold, marketed, and distributed filters under the trademarks G2®, G2® Express, and G2®X Filter Systems. Defendants deny any remaining allegations contained in Paragraph 3 of Plaintiff's Complaint.

4. The allegations contained in Paragraph 4 of Plaintiff's Complaint are not directed at Defendants and, therefore, require no response. However, to the extent the allegations contained in Paragraph 4 of Plaintiff's Complaint attempt to cast liability on Defendants, such allegations are expressly denied.

5. The allegations contained in Paragraph 5 of Plaintiff's Complaint are not directed at Defendants and, therefore, require no response. However, to the extent the allegations contained in Paragraph 5 of Plaintiff's Complaint attempt to cast liability on Defendants, such allegations are expressly denied.

JURISDICTION AND VENUE

6. Defendants do not dispute that, based on the facts as alleged by Plaintiff, which have not been and could not have been confirmed by Defendants, jurisdiction appears to be proper in the United States District Court for the Central District of California. However, Defendants deny that they are liable to Plaintiff for any amount whatsoever and deny that Plaintiff has suffered any damages whatsoever.

7. Defendants do not dispute that, based on the facts as alleged by Plaintiff, which have not been and could not have been confirmed by Defendants, venue appears to be proper in the United States District Court for the Central District of California.

GENERAL FACTUAL ALLEGATIONS

8. Defendants incorporate by reference their responses to Paragraphs 1-7 of Plaintiff's Complaint as if fully set forth herein.

9. Defendants deny the allegations contained in Paragraph 9 of Plaintiff's Complaint.

10. Defendants deny the allegations contained in Paragraph 10 of Plaintiff's Complaint.

11. Defendants deny the allegations contained in Paragraph 11 of Plaintiff's Complaint.

12. Defendants deny the allegations contained in Paragraph 12 of Plaintiff's Complaint.

13. Defendants deny the allegations contained in Paragraph 13 of Plaintiff's Complaint.

14. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegation regarding the time frame when inferior vena cava filters were first introduced on the market or the identity of manufacturers of inferior vena cava filters. Defendants deny any remaining allegations of Paragraph 14 of Plaintiff's Complaint.

15. Defendants admit that inferior vena cava filters are intended to prevent injury or death resulting from venous thrombosis and pulmonary embolism. Defendants further admit that inferior vena cava filters may be designed for permanent placement, temporary placement, or both. Defendants deny any remaining allegations of Paragraph 15 of Plaintiff's Complaint.

16. Defendants admit that the inferior vena cava is a large vein that receives blood from the lower regions of the body and delivers it to the right atrium of the heart. Defendants further admit that deep vein thrombosis and pulmonary emboli present dangerous risks to human health, including sometimes death. Defendants deny any remaining allegations of Paragraph 16 of Plaintiff's Complaint.

17. Defendants admit that certain people are at an increased risk for the development of deep vein thrombosis and pulmonary embolus, but lack sufficient information to form a belief as to the truth of the allegations as stated regarding the various risk factors which may predispose an individual to deep vein thrombosis or pulmonary emboli and thus deny them. Defendants deny any remaining allegations of Paragraph 17 of Plaintiff's Complaint.

18. Defendants admit that patients at a high risk for developing deep vein thrombosis and pulmonary embolism are frequently treated with anticoagulation therapy, including but not limited to the medications listed in Paragraph 18 of Plaintiff's Complaint. Defendants further admit that inferior vena cava filters may also be used to treat patients who are at a high risk for developing deep vein thrombosis and pulmonary embolism. Defendants lack knowledge or information sufficient to form a belief as to the truth of any remaining allegations contained in Paragraph 18 of Plaintiff's Complaint and, on that basis, deny them.

19. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the time frame when optional or retrievable inferior vena cava filters were first introduced on the market or the identity of manufacturers of retrievable inferior vena cava filters and, on that basis, deny them. Defendants admit that

Bard owns a facility where vena cava filters are manufactured, including filters under the trademarks Recovery®, G2®, G2® Express, and G2®X Filter Systems and that each of these filters is indicated for both retrievable and permanent placement. Defendants deny any remaining allegations contained in Paragraph 19 of Plaintiff's Complaint.

20. Defendants admit that the Recovery® Filter was cleared by the FDA for permanent placement on November 27, 2002, pursuant to an application submitted under Section 510(k) of the Food, Drug and Cosmetic Act. The allegations pertaining to the requirements for clearance under Section 510(k) and the scenarios for which the Recovery® Filter was cleared for use are legal conclusions to which no answer is required. To an extent a response is required, Defendants admit that the Recovery® Filter was intended to prevent injury or death resulting from venous thrombosis and pulmonary embolism, but deny any remaining allegations contained in Paragraph 20 of Plaintiff's Complaint, including all subparts thereof and including any allegations contained in Footnote 1.

21. Defendants admit that the Recovery® Filter was cleared by the FDA for retrievable placement on July 25, 2003, pursuant to an application submitted under Section 510(k) of the Food, Drug and Cosmetic Act. Defendants deny any remaining allegations contained in Paragraph 21 of Plaintiff's Complaint.

22. Defendants admit that the Recovery® Filter was on the market in 2004. Defendants deny the remaining allegations contained in Paragraph 22 of Plaintiff's Complaint.

23. Defendants admit that the Recovery® Filter consists of twelve, shape-memory Nitinol wires emanating from a central Nitinol sleeve. Defendants further admit that the twelve wires form two levels of filtration for emboli: the legs provide the lower level of filtration, and the arms provide the upper level of filtration. Defendants deny any remaining allegations contained in Paragraph 23 of Plaintiff's Complaint.

24. Defendants admit that a nickel-titanium alloy named Nitinol is used in the manufacture of the Recovery Filter and further admits that Nitinol contains shape memory.

However, to the extent Paragraph 24 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied.

25. Defendants admit that the Recovery® Filter was designed to be inserted endovascularly. Defendants further admit that the Recovery® Filter is designed to be delivered via an introducer sheath, which is included in the delivery system for the device. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 25 of Plaintiff's Complaint regarding the typical practices of physicians, including physician methods for determining successful implantation of the Recovery® Filter and, on that basis, such allegations are denied. Defendants deny any remaining allegations of Paragraph 25 of Plaintiff's Complaint.

26. Defendants deny the Recovery® Filter System was unreasonably dangerous or defective in any manner. Defendants admit that there are various well-documented complications that may occur as a result of the fracture and/or migration of any inferior vena cava filter. Defendants further admit that it is well-documented that many instances of filter fracture and/or migration result in no complications whatsoever, but, rather, are completely asymptomatic. By way of further response, Defendants state that there are incidents related to the occurrence of known complications associated with every manufacturer of inferior vena cava filters. Defendants deny the remaining allegations of Paragraph 26 of Plaintiff's Complaint, including those contained in Footnote 2.

27. Defendants deny the allegations contained in Paragraph 27 of Plaintiff's Complaint. By way of further answer, Defendants admit that there are various well-documented complications that may occur as a result of the tilt and/or perforation of any inferior vena cava filter. Defendants further admit that it is well-documented that many instances of filter tilt and/or perforation result in no complications whatsoever, but, rather, are completely asymptomatic. Defendants state that there are incidents related to the occurrence of known complications associated with every manufacturer of inferior vena cava filters.

Defendants deny any remaining allegations contained in Paragraph 27 of Plaintiff's Complaint.

28. Defendants deny the allegations contained in Paragraph 28 of Plaintiff's Complaint.

29. Defendants admit that there are various well-documented complications that may occur as the result of the fracture, perforation, tilt, and/or migration of any inferior vena cava filter. Bard states that there are incidents related to the occurrence of known complications associated with every manufacturer of inferior vena cava filters. Defendants deny the remaining allegations of Paragraph 29 of Plaintiff's Complaint.

30. Defendants admit that there are various well-documented complications that may occur as a result of the fracture, perforation, tilt and/or migration of any inferior vena cava filter. Defendants further admit that it is well documented that many instances of filter fracture, perforation, tilt, and/or migration result in no complications whatsoever but, rather, are completely asymptomatic. By way of further response, Bard states that there are incidents related to the occurrence of known complications associated with every manufacturer of inferior vena cava filters. Defendants deny the remaining allegations of Paragraph 30 of Plaintiff's Complaint, including all sub-parts thereof.

31. Defendants deny the allegations contained in Paragraph 31 of Plaintiff's Complaint.

32. Defendants deny the allegations contained in Paragraph 32 of Plaintiff's Complaint.

33. Defendants deny the allegations contained in Paragraph 33 of Plaintiff's Complaint.

34. Defendants admit that there are various well-documented complications that may occur as a result of the fracture, perforation, tilt and/or migration of any inferior vena cava filter. Defendants further admit that it is well documented that many instances of filter fracture, perforation, tilt, and/or migration result in no complications whatsoever but, rather,

are completely asymptomatic. By way of further response, Bard states that there are incidents related to the occurrence of known complications associated with every manufacturer of inferior vena cava filters. Defendants deny the remaining allegations of Paragraph 34 of Plaintiff's Complaint, including all sub-parts thereof.

35. Defendants deny the allegations contained in Paragraph 35 of Plaintiff's Complaint.

36. Defendants deny the allegations contained in Paragraph 36 of Plaintiff's Complaint.

37. Defendants admit that, as part of their continuing efforts to constantly evaluate the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are continually striving to improve the life-saving performance of those devices. The G2®, G2®X, and Eclipse™ Filters were developed in furtherance of those efforts. Defendants deny the remaining allegations contained in Paragraph 37 of Plaintiff's Complaint.

38. Defendants deny the allegations contained in Paragraph 38 as stated. Defendants admit that, as part of their continuing efforts to constantly evaluate the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are continually striving to improve the life-saving performance of those devices. The G2® Filter was developed in furtherance of those efforts. Defendants deny the remaining allegations contained in Paragraph 38 of Plaintiff's Complaint.

39. Defendants deny the allegations contained in Paragraph 39 of Plaintiff's Complaint.

40. Defendants admit the G2® Filter System was cleared by the United States Food and Drug Administration pursuant to an application submitted under Section 510(k) of the Food, Drug and Cosmetic Act. Defendants admit that the G2® Filter was originally cleared by the FDA for permanent use. Defendants further admit that the G2® Filter was subsequently cleared by the FDA for optional use as a retrievable inferior vena cava filter.

Defendants deny any remaining allegations contained in Paragraph 40 of Plaintiff's Complaint, including any allegations contained in Footnote 3.

41. Defendants admit that, as part of their continuing efforts to constantly evaluate the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are continually striving to improve the life-saving performance of those devices. The G2® Filter was developed in furtherance of those efforts. Defendants deny any remaining allegations of Paragraph 41 of Plaintiff's Complaint.

42. Defendants admit that, as part of their continuing efforts to constantly evaluate the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are continually striving to improve the life-saving performance of those devices. The G2® Filter was developed in furtherance of those efforts. Defendants deny any remaining allegations of Paragraph 42 of Plaintiff's Complaint.

43. Defendants deny the allegations contained in Paragraph 43 of Plaintiff's Complaint.

44. Defendants deny the allegations contained in Paragraph 44 of Plaintiff's Complaint.

45. Defendants admit that there are various well-documented complications that may occur as a result of the fracture, perforation, tilt, and/or migration of any inferior vena cava filter. Defendants further admit that it is well documented that many instances of filter fracture, perforation, tilt, and/or migration result in no complications whatsoever but, rather, are completely asymptomatic. By way of further response, Bard states that there are incidents related to the occurrence of known complications associated with every manufacturer of inferior vena cava filters. Defendants deny the remaining allegations of Paragraph 45 of Plaintiff's Complaint, including all sub-parts thereof.

46. Defendants admit that there are various well-documented complications that may occur as the result of the fracture, perforation, tilt, and/or migration of any inferior vena cava filter. Bard states that there are incidents related to the occurrence of known

complications associated with every manufacturer of inferior vena cava filters. By way of further response, Bard states that information available in the public domain, including the FDA MAUDE database, is not a comprehensive analysis of all instances of such complications. Defendants deny the remaining allegations of Paragraph 46 of Plaintiff's Complaint.

47. Defendants admit that there are various well-documented complications that may occur as the result of the fracture, perforation, tilt, and/or migration of any inferior vena cava filter. Bard states that there are incidents related to the occurrence of known complications associated with every manufacturer of inferior vena cava filters. By way of further response, Bard states that information available in the public domain, including the FDA MAUDE database, is not a comprehensive analysis of all instances of such complications. Defendants deny the remaining allegations of Paragraph 47 of Plaintiff's Complaint.

48. Defendants admit the G2® Express Filter System was cleared by the United States Food and Drug Administration pursuant to an application submitted under Section 510(k) of the Food, Drug and Cosmetic Act in 2008. Defendants deny any remaining allegations contained in Paragraph 48 of Plaintiff's Complaint.

49. Defendants admit the G2®X Filter System was cleared by the United States Food and Drug Administration pursuant to an application submitted under Section 510(k) of the Food, Drug and Cosmetic Act in 2008. Defendants deny any remaining allegations contained in Paragraph 49 of Plaintiff's Complaint.

50. Defendants deny the allegations contained in Paragraph 50 of Plaintiff's Complaint.

51. Defendants deny the allegations contained in Paragraph 51 of Plaintiff's Complaint.

52. Defendants deny the allegations contained in Paragraph 52 of Plaintiff's Complaint.

53. Defendants deny the allegations contained in Paragraph 53 of Plaintiff's Complaint.

SPECIFIC FACTUAL ALLEGATIONS RELATING TO PLAINTIFF

54. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 54 of Plaintiff's Complaint and, on that basis, deny them.

55. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark G2® Filter System were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark G2® Filter System. Defendants deny any remaining allegations of Paragraph 55 of Plaintiff's Complaint.

56. Defendants deny the allegations contained in Paragraph 56 of Plaintiff's Complaint.

57. Defendants deny the allegations contained in Paragraph 57 of Plaintiff's Complaint.

58. Defendants deny the allegations contained in Paragraph 58 of Plaintiff's Complaint.

59. Defendants deny the allegations contained in Paragraph 59 of Plaintiff's Complaint.

CORPORATE/VICARIOUS LIABILITY

60. Defendants deny the allegations contained in Paragraph 60 of Plaintiff's Complaint.

61. Defendants deny the allegations contained in Paragraph 61 of Plaintiff's Complaint.

62. Defendants deny the allegations contained in Paragraph 62 of Plaintiff's Complaint.

63. Defendants deny the allegations contained in Paragraph 63 of Plaintiff's Complaint.

FIRST CAUSE OF ACTION

NEGLIGENCE

64. Defendants incorporate by reference their responses to Paragraphs 1-63 of Plaintiff's Complaint as if fully set forth herein.

65. Defendants deny the allegations contained in Paragraph 65 of Plaintiff's Complaint as stated. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademarks G2® and G2® Express Filter Systems were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademarks G2® and G2® Express Filter Systems. Defendants deny any remaining allegations contained in Paragraph 65 of Plaintiff's Complaint.

66. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. Defendants deny any remaining allegations of Paragraph 66 of Plaintiff's Complaint.

67. The allegations contained in Paragraph 67 regarding Defendants' duty are legal conclusions, and no answer is required. To the extent a response is required, Defendants deny the allegations. Defendants deny the remaining allegations contained in Paragraph 67 of Plaintiff's Complaint.

68. Defendants deny the allegations contained in Paragraph 68 of Plaintiff's Complaint.

69. Defendants deny the allegations contained in Paragraph 69 of Plaintiff's Complaint, including all subparts thereof.

70. Defendants deny the allegations contained in Paragraph 70 of Plaintiff's Complaint.

71. Defendants deny the allegations contained in Paragraph 71 of Plaintiff's Complaint.

72. Defendants deny the allegations contained in Paragraph 72 of Plaintiff's Complaint, including all subparts thereof.

73. Defendants deny the allegations contained in Paragraph 73 of Plaintiff's Complaint.

74. Defendants deny the allegations contained in Paragraph 74 of Plaintiff's Complaint.

SECOND CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – FAILURE TO WARN

75. Defendants incorporate by reference their responses to Paragraphs 1-74 of Plaintiff's Complaint as if fully set forth herein.

76. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademarks G2® and G2® Express Filter Systems were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademarks G2® and G2® Express Filter Systems. The allegations regarding Defendants' legal duty are conclusions of law, requiring no response. To the extent a response is required, those allegations are denied. Defendants deny any remaining allegations contained in Paragraph 76 of Plaintiff's Complaint.

77. Defendants deny the allegations contained in Paragraph 77 of Plaintiff's Complaint.

78. Defendants deny the allegations contained in Paragraph 78 of Plaintiff's Complaint.

79. Defendants deny the allegations contained in Paragraph 79 of Plaintiff's Complaint.

80. Defendants deny the allegations contained in Paragraph 80 of Plaintiff's Complaint.

81. Defendants deny the allegations contained in Paragraph 81 of Plaintiff's Complaint.

82. Defendants deny the allegations contained in Paragraph 82 of Plaintiff's Complaint.

83. Defendants deny the allegations contained in Paragraph 83 of Plaintiff's Complaint.

84. Defendants deny the allegations contained in Paragraph 84 of Plaintiff's Complaint.

85. Defendants deny the allegations contained in Paragraph 85 of Plaintiff's Complaint.

86. Defendants deny the allegations contained in Paragraph 86 of Plaintiff's Complaint.

87. Defendants deny the allegations contained in Paragraph 87 of Plaintiff's Complaint.

88. Defendants deny the allegations contained in Paragraph 88 of Plaintiff's Complaint.

THIRD CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – DESIGN DEFECTS

89. Defendants incorporate by reference their responses to Paragraphs 1-88 of Plaintiff's Complaint as if fully set forth herein.

90. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademarks G2® and G2® Express Filter Systems were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademarks G2® and G2® Express Filter Systems. Defendants deny any remaining allegations contained in Paragraph 90 of Plaintiff's Complaint.

91. Defendants deny the allegations contained in Paragraph 91 of Plaintiff's Complaint.

92. Defendants deny the allegations contained in Paragraph 92 of Plaintiff's Complaint.

93. Defendants deny the allegations contained in Paragraph 93 of Plaintiff's Complaint.

94. Defendants deny the allegations contained in Paragraph 94 of Plaintiff's Complaint.

95. Defendants deny the allegations contained in Paragraph 95 of Plaintiff's Complaint.

FOURTH CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

96. Defendants incorporate by reference their responses to Paragraphs 1-95 of Plaintiff's Complaint as if fully set forth herein.

97. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademarks G2® and G2® Express Filter Systems were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademarks G2® and G2® Express Filter Systems. Defendants deny any remaining allegations contained in Paragraph 97 of Plaintiff's Complaint.

98. Defendants deny the allegations contained in Paragraph 98 of Plaintiff's Complaint.

99. Defendants deny the allegations contained in Paragraph 99 of Plaintiff's Complaint.

100. Defendants deny the allegations contained in Paragraph 100 of Plaintiff's Complaint.

FIFTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

101. Defendants incorporate by reference their responses to Paragraphs 1-100 of Plaintiff's Complaint as if fully set forth herein.

102. Defendants deny the allegations contained in Paragraph 102 of Plaintiff's Complaint.

103. Defendants deny the allegations contained in Paragraph 103 of Plaintiff's Complaint.

104. Defendants deny the allegations contained in Paragraph 104 of Plaintiff's Complaint.

105. Defendants deny the allegations contained in Paragraph 105 of Plaintiff's Complaint.

106. Defendants deny the allegations contained in Paragraph 106 of Plaintiff's Complaint.

107. Defendants deny the allegations contained in Paragraph 107 of Plaintiff's Complaint.

108. Defendants deny the allegations contained in Paragraph 108 of Plaintiff's Complaint.

109. Defendants deny the allegations contained in Paragraph 109 of Plaintiff's Complaint.

SIXTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY

110. Defendants incorporate by reference their responses to Paragraphs 1-109 of Plaintiff's Complaint as if fully set forth herein.

111. Defendants deny the allegations contained in Paragraph 111 of Plaintiff's Complaint as stated. Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademarks G2® and G2® Express Filter Systems were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademarks G2® and G2® Express Filter Systems. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. Defendants deny any remaining allegations contained in Paragraph 111 of Plaintiff's Complaint.

112. Defendants deny the allegations contained in Paragraph 112 of Plaintiff's Complaint.

113. Defendants deny the allegations contained in Paragraph 113 of Plaintiff's Complaint.

114. Defendants deny the allegations contained in Paragraph 114 of Plaintiff's Complaint.

115. Defendants deny the allegations contained in Paragraph 115 of Plaintiff's Complaint, including all subparts thereof.

116. Defendants deny the allegations contained in Paragraph 116 of Plaintiff's Complaint.

117. Defendants deny the allegations contained in Paragraph 117 of Plaintiff's Complaint.

118. Defendants deny the allegations contained in Paragraph 118 of Plaintiff's Complaint.

119. Defendants deny the allegations contained in Paragraph 119 of Plaintiff's Complaint.

SEVENTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

120. Defendants incorporate by reference their responses to Paragraphs 1-119 of Plaintiff's Complaint as if fully set forth herein.

121. Defendants deny the allegations contained in Paragraph 121 of Plaintiff's Complaint, including all subparts thereof.

122. Defendants deny the allegations contained in Paragraph 122 of Plaintiff's Complaint.

123. Defendants deny the allegations contained in Paragraph 123 of Plaintiff's Complaint.

124. Defendants deny the allegations contained in Paragraph 124 of Plaintiff's Complaint.

125. Defendants deny the allegations contained in Paragraph 125 of Plaintiff's Complaint.

126. Defendants deny the allegations contained in Paragraph 126 of Plaintiff's Complaint.

127. Defendants deny the allegations contained in Paragraph 127 of Plaintiff's Complaint.

128. Defendants deny the allegations contained in Paragraph 128 of Plaintiff's Complaint.

129. Defendants deny the allegations contained in Paragraph 129 of Plaintiff's Complaint.

PUNITIVE DAMAGES ALLEGATIONS

130. Defendants incorporate by reference their responses to Paragraphs 1-129 of Plaintiff's Complaint as if fully set forth herein.

131. Defendants deny the allegations contained in Paragraph 131 of Plaintiff's Complaint.

132. Defendants deny the allegations contained in Paragraph 132 of Plaintiff's Complaint, including all subparts thereof.

133. Defendants deny the allegations contained in Paragraph 133 of Plaintiff's Complaint.

134. Defendants deny the allegations contained in Paragraph 134 of Plaintiff's Complaint.

Furthermore, responding to the unnumbered Paragraph, including sub-parts, labeled "PRAYER FOR DAMAGES" and beginning "WHEREFORE," Defendants deny the allegations contained in such Paragraph, including all sub-parts thereof.

Further, responding to the unnumbered Paragraph regarding Plaintiff's allegations of negligence, Defendants deny the allegations contained in such Paragraph, including all subparts thereof. Defendants deny that Plaintiff is entitled to any relief requested in the Plaintiff's Complaint.

Further, responding to the unnumbered Paragraph regarding Plaintiff's allegations of strict liability failure to warn, Defendants deny the allegations contained in such Paragraph, including all subparts thereof. Defendants deny that Plaintiff is entitled to any relief requested in the Plaintiff's Complaint.

Further, responding to the unnumbered Paragraph regarding Plaintiff's allegations of strict liability design defect, Defendants deny the allegations contained in such Paragraph, including all subparts thereof. Defendants deny that Plaintiff is entitled to any relief requested in the Plaintiff's Complaint.

Further, responding to the unnumbered Paragraph regarding Plaintiff's allegations of strict liability manufacturing defect, Defendants deny the allegations contained in such Paragraph, including all subparts thereof. Defendants deny that Plaintiff is entitled to any relief requested in the Plaintiff's Complaint.

Further, responding to the unnumbered Paragraph regarding Plaintiff's allegations of express warranty, Defendants deny the allegations contained in such Paragraph, including all subparts thereof. Defendants deny that Plaintiff is entitled to any relief requested in the Plaintiff's Complaint.

Further, responding to the unnumbered Paragraph regarding Plaintiff's allegations of implied warranty, Defendants deny the allegations contained in such Paragraph, including all subparts thereof. Defendants deny that Plaintiff is entitled to any relief requested in the Plaintiff's Complaint.

Further, responding to the unnumbered Paragraph regarding Plaintiff's allegations of negligent misrepresentation, Defendants deny the allegations contained in such Paragraph, including all subparts thereof. Defendants deny that Plaintiff is entitled to any relief requested in the Plaintiff's Complaint.

Defendants further deny each and every allegation not specifically admitted herein.

DEFENSES

Defendants allege as affirmative defenses the following:

1. Plaintiff's Complaint filed herein fails to state a claim or claims upon which relief can be granted under Rule 12 of the Federal Rules of Civil Procedure.

2. The sole proximate cause of Plaintiff's damages, if any were sustained, was the negligence of a person or persons or entity for whose acts or omissions Defendants were and are in no way liable.

3. If Plaintiff has been damaged, which Defendants deny, any recovery by Plaintiff is barred to the extent Plaintiff voluntarily exposed himself to a known risk and/or failed to mitigate his alleged damages. To the extent Plaintiff has failed to mitigate his alleged damages, any recovery shall not include alleged damages that could have been avoided by reasonable care and diligence.

4. Plaintiff failed to exercise ordinary care for his own safety such that Plaintiff is not entitled to recover.

5. The injuries and damages allegedly sustained by Plaintiff may be due to the operation of nature or idiosyncratic reaction(s) and/or pre-existing condition(s) in Plaintiff, over which Defendants had no control.

6. Plaintiff's causes of action may be barred by the applicable statute of limitations and/or statute of repose.

7. Plaintiff's claims are barred, in whole or in part, by the doctrines of laches, waiver, and/or estoppel.

8. There was no defect in the product at issue with the result that Plaintiff is not entitled to recover against Defendants.

9. There was no causal connection between any alleged defect in the product at issue and Plaintiff's alleged damages with the result that Plaintiff is not entitled to recover against Defendants.

10. If Plaintiff has been damaged, which Defendants deny, such damages were caused by the negligence or fault of Plaintiff.

11. If Plaintiff has been damaged, which Defendants deny, such damages were caused by the negligence or fault of persons and/or entities for whose conduct Defendants are not legally responsible.

12. If Plaintiff suffered any damages or injuries, which are denied, Defendants state that Plaintiff's recovery is barred, in whole or in part, or subject to reduction under the doctrines of contributory and/or comparative negligence.

13. In the further alternative, and only in the event that it is determined that Plaintiff is entitled to recover against Defendants, recovery should be reduced in proportion to the degree or percentage of negligence, fault or exposure to products attributable to Plaintiff, any other defendants, third-party defendants, or other persons, including any party immune because bankruptcy renders them immune from further litigation, as well as any party, co-defendant, or non-parties with whom Plaintiff has settled or may settle in the future.

14. The trier of fact should apportion its award of damages among the persons who are liable according to the degree of fault of each person.

15. If Plaintiff has been damaged, which Defendants deny, the negligence or fault of Plaintiff constitutes the sole, intervening, and superseding cause of Plaintiff's alleged damages.

16. If Plaintiff has been damaged, which Defendants deny, the negligence or fault of persons and/or entities for whose conduct Defendants are not legally responsible constitutes the sole, intervening, and superseding cause of Plaintiff's alleged damages.

17. If Plaintiff has been damaged, which Defendants deny, the actions of persons or entities for whose conduct Defendants are not legally responsible and the independent knowledge of these persons or entities of the risks inherent in the use of the product and other independent causes, constitute an intervening and superseding cause of Plaintiff's alleged damages.

18. If Plaintiff has been damaged, which Defendants deny, such damages were caused by unforeseeable, independent, intervening, and/or superseding events for which Defendants are not legally responsible.

19. If Plaintiff has been damaged, which Defendants deny, such damages were caused by abuse, misuse, user error and/or modification of the product at issue for which Defendants were and are in no way liable.

20. Defendants made no warranties of any kind, express or implied, including any alleged implied warranty of merchantability or implied warranty of fitness for a particular purpose, or any representations of any nature whatsoever to Plaintiff. To the extent applicable, Plaintiff's breach of warranty claims are barred by a lack of privity between Plaintiff and Defendants. To the extent Plaintiff makes warranty claims, whether express or implied, the claims are barred or limited by any and all express conditions or disclaimers, by Plaintiff's lack of reliance on any such warranties, and by waiver.

21. Plaintiff's claims for breach of implied warranty must fail because the product was not used for its ordinary purpose.

22. Plaintiff's claim for breach of warranty is barred because Plaintiff did not first give notice of any alleged defect of the product to Defendants.

23. Defendants neither had nor breached any alleged duty to warn with respect to the product, with the result that Plaintiff is not entitled to recover.

24. Plaintiff's failure to warn claims are barred by virtue of the intervention of the learned intermediary or intermediaries to whom Defendants discharged their duties to warn.

25. The conduct of Defendants and the subject product at all times conformed with the Federal Food, Drug and Cosmetic Act, and other pertinent federal statutes and regulations. Accordingly, Plaintiff's claims are barred, in whole or in part, under the doctrine of federal preemption, and granting the relief requested would impermissibly infringe upon and conflict with federal laws, regulations, and policies in violation of the Supremacy Clause of the United States Constitution.

26. If Plaintiff recovers from Defendants, Defendants are entitled to contribution, set-off, and/or indemnification, either in whole or in part, from all persons or entities whose negligence or fault proximately caused or contributed to cause Plaintiff's alleged damages.

27. Plaintiff's claims are, or may be, barred, in whole or in part, to the extent that Plaintiff has released, settled with, entered into an accord and satisfaction, or otherwise compromised their claims. Defendants are entitled to a set-off for the entire amount of proceeds Plaintiff has, or may, recover from all other sources.

28. Should Defendants be held liable to Plaintiff, which liability is specifically denied, Defendants would be entitled to a setoff for the total of all amounts paid to Plaintiff from all collateral sources.

29. Defendants assert any and all defenses, claims, credits, offsets, or remedies provided by the Restatements (Second and Third) of Torts and reserve the right to amend their Answer to file such further pleadings as are necessary to preserve and assert such defenses, claims, credits, offsets, or remedies.

30. The device at issue was not sold in a defective condition unreasonably dangerous to the user or consumer, and therefore Plaintiff's claims are barred under the Restatement (Second) of Torts: Products Liability § 402A and comments thereto, and comparable provisions of the Restatement (Third) of Torts (Products Liability).

31. Plaintiff's claims are barred because the methods, standards, warnings, and instructions used in manufacturing and/or marketing the product at issue conformed with the generally recognized, reasonably available, and reliable state of knowledge when the product was manufactured and marketed.

32. Plaintiff's claims are barred because the methods, standards, warnings, and instructions used in manufacturing and/or marketing the product at issue conformed to industry custom/usage standards and/or legislative, administrative, and/or regulatory standards.

33. At all relevant times during which the device at issue was designed, developed, manufactured, and sold, the device was reasonably safe and reasonably fit for its intended use, was not defective or unreasonably dangerous, and was accompanied by proper warnings, information, and instructions, all pursuant to generally recognized prevailing industry standards and state-of-the-art in existence at the time.

34. The design complained of in Plaintiff's Complaint, the alleged defects of the product, and/or any alternative design claimed by Plaintiff were not known and, in light of the existing, reasonably-available scientific and technological knowledge, could not have been known at the time the product at issue was designed, manufactured, and sold. Any alleged alternative design was not scientifically or technologically feasible or economically practical.

35. Defendants specifically plead all affirmative defenses under the Uniform Commercial Code ("UCC") now existing or which may arise in the future, including those defenses provided by UCC §§ 2-607 and 2-709.

36. No act or omission of Defendants was malicious, willful, wanton, reckless, or grossly negligent, and, therefore, any award of punitive damages is barred.

37. In response to Plaintiff's demand for punitive damages, Defendants specifically incorporate by reference any and all standards of limitations regarding the determination and/or enforceability of punitive damages awards that arose in the decisions of *BMW of No. America v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S. Ct. 1513 (2003); and *Exxon Shipping Co. v. Baker*, No. 07-219, 2008 U.S. LEXIS 5263 (U.S. June 25, 2008) and their progeny as well as other similar cases under both federal and state law.

38. Plaintiff's claim for punitive damages is in contravention of the rights of Defendants under the following provisions of the United States Constitution and analogous provisions of the California Constitution:

Plaintiff's claims for punitive or exemplary damages violate, and are therefore barred by, the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the Constitution of the United States of America on grounds including the following:

(a) it is a violation of the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution to impose punitive damages, which are penal in nature, against a civil defendant upon the plaintiff satisfying a burden of proof which is less than the "beyond a reasonable doubt" burden of proof required in criminal cases;

(b) the procedures pursuant to which punitive damages are awarded may result in the award of joint and several judgments against multiple defendants for different alleged acts of wrongdoing, which infringes upon the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution;

(c) the procedures to which punitive damages are awarded fail to provide a reasonable limit on the amount of the award against defendant, which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution;

(d) the procedures pursuant to which punitive damages are awarded fail to provide specific standards for the amount of the award of punitive damages which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution;

(e) the procedures pursuant to which punitive damages are awarded result in the imposition of different penalties for the same or similar acts, and thus violate the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution;

(f) the procedures pursuant to which punitive damages are awarded permit the imposition of punitive damages in excess of the maximum criminal fine for the

same or similar conduct, which thereby infringes upon the Due Process Clause of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution;

(g) the procedures pursuant to which punitive damages are awarded permit the imposition of excessive fines in violation of the Eighth Amendment of the United States Constitution;

(h) the award of punitive damages to the plaintiff in this action would constitute a deprivation of property without due process of law; and

(i) the procedures pursuant to which punitive damages are awarded permit the imposition of an excessive fine and penalty.

39. This case may be subject to dismissal or transfer under the doctrine of *forum non conveniens*.

40. The device at issue complied with any applicable product safety statute or administrative regulation, and therefore Plaintiff's defective design and warnings-based claims are barred under the Restatement (Third) of Torts: Products Liability § 4, *et seq*. and comments thereto.

41. To the extent Plaintiff's Complaint alleges misrepresentation or fraud, these allegations do not comply with the requisite of particularity under applicable procedural rules and/or law.

42. Plaintiff's claims are barred because there was insufficiency of process and/or insufficiency of service of process.

Defendants intend to rely upon any additional affirmative defenses under California law that become available during the course of investigation and/or discovery and reserves the right to amend its Answer to assert these defenses.

43. Defendants allege that the liability of Defendants, if any, is subject to the limitations set forth in the Fair Responsibility Act of 1986 (Cal. Civ. Code §§ 1431-1431.5).

44. Plaintiff's claims for design defect are barred as a matter of law under Comment k to the Restatement (Second) of Torts: Products Liability §402A, and California case law upholding and applying that provision, including but not limited to, *Brown v. Superior Court*, 44 Cal. 3d 1049 (1988); *Hufft v. Horowitz*, 4 Cal. App. 4th 8, 18 (1992); and *Artiglio v. Superior Court*, 22 Cal. App. 4th 1388, 1397 (1994).

45. Plaintiff's claims for breach of implied warranty is barred under Cal. Civ. Code § 1793.02(e)(3), which prohibits claims for breach of the implied warranty of fitness against manufacturers of assistive medical devices. *Fender v. Medtronic, Inc.*, 887 F. Supp. 1326, 1332–33 (E.D. Cal. 1995).

46. Plaintiff's claims are barred, in whole or in part, because the promotion of the products at issue is protected by the First Amendment of the United States Constitution and similar provisions of the California State Constitution.

47. Plaintiff's claims are barred, in whole or in part, due to the doctrine of spoliation and the failure to properly preserve evidence necessary to the determination of the alleged claims against Defendants.

48. At all relevant times herein, Plaintiff's physicians were in the position of sophisticated purchasers, fully knowledgeable and informed with respect to the risks and benefits of the device.

49. Plaintiff's claims are barred, in whole or in part, by the doctrine of *res judicata*.

50. Plaintiff's claims are barred, in whole or in part, by the economic loss doctrine.

REQUEST FOR JURY TRIAL

Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. demand a trial by jury on all issues appropriate for jury determination.

WHEREFORE, Defendants aver that Plaintiff is not entitled to the relief demanded in the Plaintiff's Complaint, and these Defendants, having fully answered, pray that this action against them be dismissed and that they be awarded their costs in defending this action and that they be granted such other and further relief as the Court deems just and appropriate.

This 9th day of November, 2015.

s/Richard B. North, Jr.
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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on November 9, 2015, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send notification of such filing to all counsel of record.

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